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EXAMINER	
HA, JULIE	
ART UNIT	PAPER NUMBER
1654	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,103	PETZELBAUER ET AL.	
	Examiner	Art Unit	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACT

Amendment after Non-final office action filed on May 27, 2010 is acknowledged. New claims 29-64 have been added. Claims 17-64 are pending and examined on the merits in this office action.

Withdrawn Objection and Rejection

1. Sequence non-compliance is hereby withdrawn in view of Applicant's filing of a sequence listing on March 05, 2010.

2. Objection to claim 17 due to minor informality is hereby withdrawn in view of Applicant's amendment to the claim.

3. Rejection of claims 23-28 under 35 U.S.C. 112, second paragraph is hereby withdrawn in view of Applicant's amendment to the claims.

Maintained Rejections

35 U.S.C. 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 remain/are rejected under 35 U.S.C. 102(e) as being anticipated by Petzelbauer P (US 2004/0192596 A1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

5. Petzelbauer teaches the same formulae I and II as the instant formula II, see paragraphs [0002] and [0006]. Furthermore, GHRPLDKKREEAPSLRPAPPPISGGGYR (see SEQ ID NO: 294) that is the same as the one claimed in instant claims 17-22 and the instant SEQ ID NOS: 2 and 3, meeting the limitation of claims 17-22. Furthermore, the instant claims 23-28 recite "...wherein the shock is associated with one or more groups comprising bacterial toxins, haemorrhagic shock following viral infection...infectious agents or autoimmune diseases, organ failure...and so on (see claims 23-28). Petzelbauer reference teaches the method of preventing inflammation in a subject comprising administering to the subject an effective amount of a peptide having the general formula II, wherein the inflammation is due to a condition selected from the group consisting of an infection, an autoimmune condition, a rheumatic disorder, or a disorder of the immune system (see claims 14 and 21). The reference further teaches a method of treating rejection of a transplanted tissue in a subject comprising administering to the subject an effective amount of peptide of formula (II)

(see claims 24-26). Since the cause that leads to inflammation and shock is the same, the method of treating inflammation would necessarily treat shock, and vice versa.

Response to Applicant's Arguments

6. Applicant argues that "US 2004/0192596 is published U.S. patent application which are continuations of International application PCT/AT2001/00387, published as WO 02/48180. As reference WO 02/48180 was found to not be of particular relevance to the determination of novelty and inventive step with regard to the subject matter presently claimed.

7. Applicant's arguments have been fully considered have not been found persuasive. US 2004/0192596 teaches the same formula II as the instant formula II, and teaches the peptide sequence that is the same as instant SEQ ID NO: 8 (see SEQ ID NO: 294). The reference teaches the same active method steps as instant claims. The reference teaches the method of preventing inflammation in a subject comprising administering to the subject an effective amount of a peptide having the formula II, wherein the inflammation is due to a condition selected from the group consisting of an infection, an autoimmune condition, a rheumatic disorder, or a disorder of the immune system (see claims 14 and 21). Since the cause that leads to inflammation and shock is the same, the method of treating inflammation would necessarily treat shock. In regards to Applicant's argument that WO 02/48180 was not found to be of particular relevance, Applicant is reminded that the instant application is a US application and is examined under US guidelines. There is no relevance as to what the International office

considered to be relevant to the determination of novelty and inventive step. The active method steps of instant claims are taught by US 2004/0192596. Therefore, the reference meets the limitation of instant claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62.

8. Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 remain/are rejected under 35 U.S.C. 102(e) as being anticipated by Petzelbauer P (US 2007/0037749 A1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

9. Petzelbauer teaches the same formula II as the instant formula II, see paragraphs [0007] and [0011]. Furthermore, the reference teaches the sequences GHRPLDKKREEAPSLRPAPPPISGGGYR (see SEQ ID NO: 294) that is the same as the one claimed in instant claims 17-22 and the instant SEQ ID NOS: 2 and 3, meeting the limitation of claims 17-22. The reference teaches that the invention consist of the preparation of pharmaceutical compositions for the therapy or prevention of local and/or generalized inflammations in the body in case of infectious genesis, based upon autoimmune reaction, based upon a rheumatic disease, based upon a disorder in the immune system…for the prevention and/or therapy of the rejection occurring after organ

transplants…" (see paragraph [0034]). The instant claims 23-28 recite "…wherein the shock is associated with one or more groups comprising bacterial toxins, haemorrhagic shock following viral infection…infectious agents or autoimmune diseases, organ failure…and so on (see claims 23-28). Claim 3 of the reference claims that the inflammation is due to a condition selected from the group consisting of an infection, an autoimmune condition, a rheumatic disorder, or a disorder of the immune system (see claim 3). Since the cause that leads to inflammation and shock is the same, and the reference claims a method of treating inflammation in a subject (see claims 1-4), a method of inhibiting inflammation of a transplanted tissue in a subject (see claims 5-6), the method of treating inflammation and inhibiting inflammation in a transplanted tissue would necessarily treat shock, and vice versa.

Response to Applicant's Arguments

10. Applicant argues that "US 2007/0037749 is published U.S. patent application which are continuations of International application PCT/AT2001/00387, published as WO 02/48180. As reference WO 02/48180 was found to not be of particular relevance to the determination of novelty and inventive step with regard to the subject matter presently claimed.

11. Applicant's arguments have been fully considered have not been found persuasive. US 2007/0037749 teaches the same formula II as the instant formula II, and teaches the peptide sequence that is the same as instant SEQ ID NO: 8 (see SEQ ID NO: 294). The reference teaches the same active method steps as instant claims. Claim

3 of the reference claims that the inflammation is due to a condition selected from the group consisting of an infection, an autoimmune condition, a rheumatic disorder, or a disorder of the immune system (see claim 3). Since the cause that leads to inflammation and shock is the same, and the reference claims a method of treating inflammation in a subject (see claims 1-4), a method of inhibiting inflammation of a transplanted tissue in a subject (see claims 5-6), the method of treating inflammation and inhibiting inflammation in a transplanted tissue would necessarily treat shock.
In regards to Applicant's argument that WO 02/48180 was not found to be of particular relevance, Applicant is reminded that the instant application is a US application and is examined under US guidelines. There is no relevance as to what the International office considered to be relevant to the determination of novelty and inventive step. The active method steps of instant claims are taught by US 2007/0037749. Therefore, the reference meets the limitation of instant claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62.

12. Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Petzelbauer, Peter (WO 02/48180 A2, filed with IDS, published on June 20, 2002). This publication is in German, and machine translation is used and provided.

13. WO 02/48180 A2 teaches peptides or proteins of general formula (I and II) where R_1 and R_2 are independently hydrogen, a saturated or unsaturated hydrocarbon group with 1 to 3 carbon atoms, Z_1 is histidine or proline, Z_2 is an arginine, a peptide group or protein group with arginine at the initial terminus (see abstract, claims 1-2), meeting the

limitation of instant claims 17-22. The reference teaches the same sequence as instant sequence DKKREEAPSLRPAPPPISGGGYR (see SEQ ID NO: 11 and claim 5), meeting the limitation of claim 17. Furthermore, the reference teaches the sequence GHRPLDKKREEAPSLRPAPPPISGGGYR (see SEQ ID NO: 11), meeting the limitation of claims 17-22. The reference teaches the method of treating inflammation due to inflammation of the body, autoimmune reaction, genetic disease, trauma, organ transplant and so on (see claims 7-17). Furthermore, the instant claims 23-28 recite "...wherein the shock is associated with one or more groups comprising bacterial toxins, haemorrhagic shock following viral infection...infectious agents or autoimmune diseases, organ failure...and so on (see claims 23-28). WO 02/48180 A2 reference teaches the method of preventing inflammation in a subject comprising administering to the subject an effective amount of a peptide having the general formula II, wherein the inflammation is due to a condition selected from the group consisting of an infection, an autoimmune condition, a rheumatic disorder, or a disorder of the immune system (see claims 7-17). Since the cause that leads to inflammation and shock is the same, the method of treating inflammation would necessarily treat shock, and vice versa. Thus, the reference anticipates instant claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62.

Response to Applicant's Arguments

14. Applicant argues that "Although, shock may be the result of specific types of inflammation, not all cases of shock include inflammation as a symptom. Thus,

Applicants argue that methods of treating inflammation are distinct from methods of treating shock...the disclosure of method of treating shock or preventing inflammation in reference WO 02/48180 was found to not be of particular relevance to the determination of novelty and inventive step of methods of treating shock in the presently claimed invention."

15. Applicant's arguments have been fully considered but have not been found persuasive. The reference teaches all of the active method steps of instant application. The reference teaches the method of preventing inflammation in a subject comprising administering to the subject an effective amount of a peptide having the general formula II and the same peptide sequence as instant SEQ ID NO: 8 (see SEQ ID NO: 11), wherein the inflammation is due to a condition selected from the group consisting of an infection, an autoimmune condition, a rheumatic disorder, or a disorder of the immune system (see claims 7-17). The reference teaches medicaments for the therapy or prevention of local and/or generalized inflammations of the body with infectious genesis, on basis of an autoimmune reaction, on basis of a rheumatoid disease, on basis of a disturbance of the immune system, on basis of genetic disease, to the prevention and/or therapy of the repulsion reaction with organ transplant ions, the arteriosclerosis, the Reperfusions traumas, on basis of arterioskelerotischer and/or thrombotic diseases and increased Fibrin deposition (see p. 2 of translated copy). Since the cause that leads to inflammation and shock is the same, the method of treating inflammation would necessarily treat shock, and vice versa. Thus, the reference anticipates instant claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62.

Obviousness Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 remain/are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 7,271,144. Although the conflicting claims are not identical, they are not patentably distinct from each other because if one practiced the claimed invention of instant application, one would achieve the claimed invention of U.S. Patent No. '144 and vice versa.

18. Instant claims are drawn to a method for treating shock comprising administering to a subject in need of such treatment an effective amount of a peptide of Formula II.

19. Claims 1-4 of U.S. Patent No. '144 are drawn to a method of treating inflammation in a subject comprising administering to the subject a peptide of SEQ ID

NO: 294, wherein the inflammation is due to a condition selected from the group consisting of an infection, an autoimmune condition, a rheumatic disorder, or a disorder of the immune system.

20. U.S. Patent No. '144 claims the peptide of formula II of the instant claims, and teaches a method of treating inflammation in a subject comprising administering to the subject a peptide SEQ ID NO: 294, which is the same as the instant claims 17-22, and also teaches that the inflammation is due to the same conditions (infection, autoimmune disease, a rheumatoid disorder, or a disorder of the immune system) (see claim 3). Therefore, if one practiced the claimed invention of the instant claims, one would necessarily achieve the claimed invention of the U.S. Patent No. '144 and vice versa.

21. Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 remain/are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 11/899,611. Although the conflicting claims are not identical, they are not patentably distinct from each other because if one practiced the claimed invention of instant claims, one would necessarily achieve the claimed invention of copending application and vice versa.

22. Instant claims are drawn to a method for treating shock comprising administering to a subject in need of such treatment an effective amount of a peptide of Formula II. Claims 23-28 are drawn to a method of treating shock, wherein shock is due to myocardial infarction, vascular surgery...surgical procedures and stroke, and organ dysfunction of grafter organs, and so forth.

23. Claims 1-4 of copending application are drawn to a method of treating reperfusion injury in a subject comprising administering to the subject a peptide of SEQ ID NO:294, that is the same as the instant SEQ ID NO:3. The specification of the reference discloses that a healing effect occurs with a drug for the therapy and/or prevention of a reperfusion trauma following a surgically or pharmaceutically induced restoration of the blood flow such as, after cardiac infarction, apoplectic stroke, after vascular surgery...(see paragraph [0066] of instant specification US 2009/0137464 A1).

24. Therefore, if one of ordinary skill in the art practiced the claimed invention of the instant claims, one would necessarily achieve the claimed invention of copending application 11/899,611, and vice versa.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

25. Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 remain/are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 7,494,973. Although the conflicting claims are not identical, they are not patentably distinct from each other because if one practiced the claimed invention of instant claims, one would necessarily achieve the claimed invention of copending application, and vice versa.

26. Instant claims are drawn to a method for treating shock comprising administering to a subject in need of such treatment an effective amount of a peptide of Formula II.

27. Claims 1-3 of US Patent No. '973 are drawn to a method of treating rejection of a transplanted tissue in a subject comprising administering to the subject a peptide of SEQ ID NO: 294. The specification of the reference teaches that the invention consist in the preparation of pharmaceutical compositions for the therapy or prevention of local and/or generalized inflammation in the body in case of infectious genesis, based upon an auto-immune reaction, based upon a rheumatic disease, based upon a disorder in the immune system, based upon genetic disease, for the prevention and/or therapy of the rejection occurring after organ transplants, and so on (see column 4, lines 19-36).

28. The instant claims 23-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 claim that the shock is associated with one or more of the group comprising bacterial toxins, hemorrhagic shock following viral infection…infectious agents or autoimmune diseases, organ failure after organ injury…vascular surgery, clamping of organs…organ dysfunction of grafted organs, and so on.

29. Therefore, if one practiced the claimed invention of the instant claims, one would necessarily achieve the claimed invention of the U.S. Patent No. '973 and vice versa.

Response to Applicant's Arguments

30. Applicant argues that "US patent No. 7,271,144, US patent No. 7,494,973 and US application 11/899,611 share the same disclosure...the methods of treating shock disclosed in the instant application are neither anticipated nor rendered obvious by methods of treating inflammation disclosed in US patent 7,271,144, US patent No. 7,494,973 and US application 11/899,611.

31. Applicant's arguments have been fully considered but have not been found persuasive. US Patent No. 7,271,144, US Patent No. 7,494,973 and US application 11/899,611 teach all of the active method steps of instant claims. US Patent No. '144, '973 and US application '611 teach the method of treating inflammation and tissue transplant and reperfusion. Since the cause that leads to inflammation and shock is the same, and the reference claims a method of treating inflammation in a subject, a method of inhibiting inflammation of a transplanted tissue in a subject, the method of treating inflammation and inhibiting inflammation in a transplanted tissue would necessarily achieve treatment of shock.

32. Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 remain/are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6-7 of copending Application No. 12/121,533. Although the conflicting claims are not identical, they are not patentably distinct from each other because if one practiced the claimed invention of instant claims, one would necessarily achieve the claimed invention of copending application and vice versa.

33. Instant claims are drawn to a method for treating shock comprising administering to a subject in need of such treatment an effective amount of a peptide of Formula II. Claims 23-28 are drawn to a method of treating shock, wherein shock is due to myocardial infarction, vascular surgery...surgical procedures and stroke, and organ dysfunction of grafter organs, and so forth.

34. Claims 6-7 of copending application are drawn to a pharmaceutical composition containing a compound of the general formula (I) and medical use of a compound of the general formula (I). The instant specification discloses that diseases belonging to the group are those in context with autoimmunity…a healing effect harmful to the tissue…important to the treatment of shock (see p. 11).

35. Therefore, if one of ordinary skill in the art practiced the claimed invention of the instant claims, one would necessarily achieve the claimed invention of copending application 12/121,533, and vice versa.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

36. Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 remain/are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-7 of copending Application No. 12/121,544. Although the conflicting claims are not identical, they are not patentably distinct from each other because if one practiced the claimed invention of instant claims, one would necessarily achieve the claimed invention of copending application and vice versa.

37. Instant claims are drawn to a method for treating shock comprising administering to a subject in need of such treatment an effective amount of a peptide of Formula II. Claims 23-28 are drawn to a method of treating shock, wherein shock is due to myocardial infarction, vascular surgery...surgical procedures and stroke, and organ dysfunction of grafter organs, and so forth.

38. Claims 6-7 of copending application are drawn to a pharmaceutical composition comprising peptide of formula I, medical use of a compound of the general formula (I). The medical use is not defined in the claims. The instant specification discloses that diseases belonging to this group are those in context with autoimmunity… a healing effect harmful to the tissue…important to the treatment of shock (see p. 11).

39. Therefore, if one of ordinary skill in the art practiced the claimed invention of the instant claims, one would necessarily achieve the claimed invention of copending application 12/121,544, and vice versa.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

40. Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 remain/are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 4-5 of copending Application No. 12/158,670. Although the conflicting claims are not identical, they are not patentably distinct from each other because if one practiced the claimed invention of instant claims, one would necessarily achieve the claimed invention of copending application and vice versa.

41. Instant claims are drawn to a method for treating shock comprising administering to a subject in need of such treatment an effective amount of a peptide of Formula II. Claims 23-28 are drawn to a method of treating shock, wherein shock is due to

myocardial infarction, vascular surgery...surgical procedures and stroke, and organ dysfunction of grafter organs, and so forth.

42. Claims 1-2 and 4-5 of copending application are drawn to a method for treating hemorrhagic shock or the sequels thereof, comprising administering to an animal a peptide comprising the N-terminal sequence GHRPLDKKREEAPSLRPAPPPISGGGYR, that is the same as the instant SEQ ID NO:3.

43. Since the copending application is drawn to a method of treating hemorrhagic shock, if one of ordinary skill in the art practiced the claimed invention of the instant claims, one would necessarily achieve the claimed invention of copending application 12/158,670, and vice versa.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Applicant's Arguments

44. Applicant requests an Ex parte Quayle action to address these matters once prosecution on the merits is closed. Applicant argues that "at that time Applicants will consider the need to file one or more terminal disclaimers over the aforementioned patent applications."

45. Applicant's arguments have been fully considered but have not been found persuasive. Until properly executed terminal disclaimers are filed and approved by the Office, Double Patenting rejections are maintained.

New Rejection

35 U.S.C. 103

46. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

47. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

48. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

49. Claims 17-32, 35-38, 41-44, 47-50, 53-56 and 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petzelbauer, Peter (WO 02/48180 A2, filed

with IDS, published on June 20, 2002, published in German, machine translation provided in the previous office action) in view of Bevec et al (US 2004/0122058 A1, filed on Mar 6, 2002).

50. WO 02/48180 A2 teaches peptides or proteins of general formula (I and II) where R_1 and R_2 are independently hydrogen, a saturated or unsaturated hydrocarbon group with 1 to 3 carbon atoms, Z_1 is histidine or proline, Z_2 is an arginine, a peptide group or protein group with arginine at the initial terminus (see abstract, claims 1-2), meeting the limitation of instant claims 17-22. The reference teaches the same sequence as instant sequence DKKREEAPSLRPAPPPISGGGYR (see SEQ ID NO: 11 and claim 5), meeting the limitation of claim 17. Furthermore, the reference teaches the sequence GHRPLDKKREEAPSLRPAPPPISGGGYR (see SEQ ID NO: 11), meeting the limitation of claims 17-22. The reference teaches the method of treating inflammation due to inflammation of the body, autoimmune reaction, genetic disease, trauma, organ transplant and so on (see claims 7-17). Furthermore, the instant claims 23-28 recite "...wherein the shock is associated with one or more groups comprising bacterial toxins, haemorrhagic shock following viral infection...infectious agents or autoimmune diseases, organ failure...and so on (see claims 23-28). WO 02/48180 A2 reference teaches the method of preventing inflammation in a subject comprising administering to the subject an effective amount of a peptide having the general formula II, wherein the inflammation is due to a condition selected from the group consisting of an infection, an autoimmune condition, a rheumatic disorder, or a disorder of the immune system (see claims 7-17). Since the cause that leads to inflammation and shock is the same, the

method of treating inflammation would necessarily treat shock, and vice versa. Thus, the reference anticipates instant claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62. The difference between the reference and the instant claims is that the reference does not teach that the viral infection is caused by filovirus. The reference teaches the treatment of infection.

51. However, Bevec et al teach that hemorrhagic fever and/or hemorrhagic shock syndromes are induced by a filovirus, an arenavirus, a flavivirus, or bunyavirus (see paragraphs [0068]-[0069]).

52. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings and try treatment of shock on those infected with viral infection caused by filovirus, arenaviridae, bunyaviridae or flavivirus, since the primary reference teaches the treatment of all infections, and Bevec teaches subspecies of viral infections that lead to inflammatory conditions (see abstract). One of ordinary skill in the art would be motivated to try, since Petzelbauer reference teaches treatment of all infections, and since the cause of at leads to inflammation and shock is the same, one would be motivated to treat shock with the peptide taught by Petzelbauer reference. There is a reasonable expectation of success, Petzelbauer reference teaches treatment of all infections, an autoimmune condition, a rheumatic disorder, and a disorder of the immune system, and the cause that leads to inflammation and shock is the same, one would expect administration of the same compound to the same patient population would lead to treatment of shock.

53. Claims 17-28, 30-33, 36-39, 42-45, 48-51, 54-57 and 60-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petzelbauer, Peter (WO 02/48180 A2, filed with IDS, published on June 20, 2002, published in German, machine translation provided in the previous office action) in view of Thurkauf et al (WO 02/49993 A2).

54. The teachings of Petzelbauer reference is described, *supra*. The difference between the reference and the instant claims is that the reference does not teach lung injury.

55. However, Thurkauf et al teach that sepsis, septic shock…inflammation associated with burns, lung injury, myocardial infarction, coronary thrombosis, vascular occlusion, post-surgical vascular reocclusion…tissue graft rejection and so on (see claims 148-149).

56. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings and try treatment of shock on those having lung injury, since the primary reference teaches the treatment of all infections, and inflammation due to a disorder of the immune system and Thurkauf et al teach that inflammation is associated with lung injury, sepsis, shock and other diseases and medical conditions. One of ordinary skill in the art would be motivated to try, since Petzelbauer reference teaches treatment of all infections, and inflammation due to a disorder of the immune system, and since the cause of at leads to inflammation and shock is the same, one would be motivated to treat shock with the peptide taught by Petzelbauer reference. There is a reasonable expectation of success, Petzelbauer reference teaches treatment of all infections, an autoimmune condition, a rheumatic disorder, and a disorder of the

immune system, and Thurkauf et al teach that inflammation is associated with lung injury, sepsis, shock post-surgical vascular reocclusion…tissue graft rejection and so on, and the cause that leads to inflammation and shock is the same, one would expect administration of the same compound to the same patient population would lead to treatment of shock.

57. Claims 17-28, 30-34, 36-40, 42-46, 48-52, 54-58, and 60-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petzelbauer, Peter (WO 02/48180 A2, filed with IDS, published on June 20, 2002, published in German, machine translation provided in the previous office action) in view of Yat (WO 94/07815).

58. The teachings of Petzelbauer reference is described, *supra*. The difference between the reference and the instant claims is that the reference does not teach shock from Dengue fever and lung injury.

59. However, Yat reference teaches inflammatory diseases such as asthma, bronchial allergy, chronic inflammation…necrosis in myocardial infarction…transplant rejection and that shock accompanies Dengue fever (see column 3, lines 51-53).

60. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings and try treatment of shock on those having lung injury and Dengue fever, since the primary reference teaches the treatment of all infections, and inflammation due to a disorder of the immune system, and Yat teaches that inflammation is associated with lung injury and other diseases and medical conditions such as Dengue fever. One of ordinary skill in the art would be motivated to try, since

Petzelbauer reference teaches treatment of all infections, and inflammation due to a disorder of the immune system, and since the cause of at leads to inflammation and shock is the same, one would be motivated to treat shock with the peptide taught by Petzelbauer reference. There is a reasonable expectation of success, Petzelbauer reference teaches treatment of all infections, an autoimmune condition, a rheumatic disorder, and a disorder of the immune system, and Yat teaches that inflammation is associated with lung injury, transplant rejection and shock accompanying Dengue fever and so on, and the cause that leads to inflammation and shock is the same, one would expect administration of the same compound to the same patient population would lead to treatment of shock.

Conclusion

61. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). No claim is allowed.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/
Primary Examiner, Art Unit 1654